

DEC 1 2000

K003421

510(k) Summary

Name of Sponsor:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

510(k) Contact:

Marcia J. Arentz
Senior Regulatory Associate
Phone: (219) 371-4944
FAX: (219) 371-4940

Trade Name:

DePuy C-Stem™ System

Common Name:

Total Hip Joint Replacement Prosthesis

Classification:

Class II Device per 21 CFR 888.3350:
Hip joint metal/polymer semi-constrained cemented prosthesis

Device Product Code:

Code: **87JDI**

No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for femoral hip stems.

Substantially Equivalent Device:

DePuy C-Stem System K982918

Device Descriptions:

The DePuy C-Stem System hip stem is a collarless, slim-profiled, triple-tapered polished stem manufactured from stainless steel. The C-Stem system includes a gelatin end cap and PMMA centralizers.

The design utilizes a neck with a taper for attachment of femoral ball heads. Cobalt-chromium-molybdenum alloy, Ortron 90 Stainless Steel and Zirconia ceramic femoral ball heads are used with the C-Stem prosthesis to provide the femoral prosthetic articular surface for the total hip arthroplasty. The femoral ball head fits into a DePuy acetabular cup prosthesis.

Intended use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

000006

Indications for use:

Total hip replacement is indicated in the following conditions:

1. Severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Substantial equivalence:

The fundamental scientific technology of the C-Stem System and hip stem have not changed from the FDA cleared ~~the~~ DePuy C-Stem System (K982918). The intended use and indications for use have not changed from the FDA-cleared DePuy C-Stem system (K931641). The new size C-Stem hip prosthesis is manufactured from the same stainless steel as the previously cleared sizes.

Based on conformance with the design control procedures requirements as specified in 21 CFR 820.30, similarities of design, commonly used materials, identical sterilization processes, the same indications for use and intended use, DePuy believes that the C-Stem System to be substantially equivalent to the FDA cleared C-Stem System originally cleared in K982918.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 1 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Marcia Arentz
Senior Regulatory Associate
700 Orthopaedic Drive
Post Office Box 988
Warsaw, Indiana 46581-0988

Re: K003421
Trade Name: DePuy C-Stem™ System
Regulatory Class: II
Product Code: JDI
Dated: November 2, 2000
Received: November 3, 2000

Dear Ms. Arentz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Mark N. Melburn

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): 003421

Device Name: DePuy C-Stem™ System

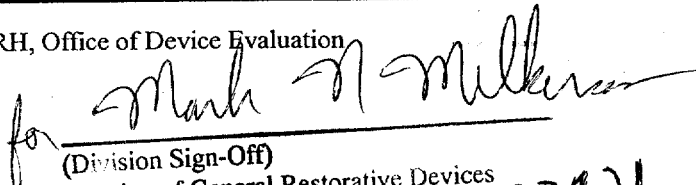
Indications for Use:

The DePuy C-Stem System is indicated for cemented use as the femoral component in total hip arthroplasty.

Total hip ~~arthroplasty is intended to provide increased patient mobility and reduce pain by replacing~~ the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Concurrence of CDRH, Office of Device Evaluation

for 
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003421

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

000003